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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,382	04/08/2004	Matthew Peterson	TPIP039	8458

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TRANSFORM PHARMACEUTICALS, INC.
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LEXINGTON, MA 02421

EXAMINER

REYES, HECTOR M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,382

Applicant(s)

PETERSON ET AL.

Examiner

Hector M Reyes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/08/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESTRICTION REQUEST

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 drawn to different gabapentin salts and pharmaceutical compositions thereof, as described in the said claims, classified in multiple classes and multiple subclasses. ***A single disclosed species (salt) is hereby requested for search purpose.***
- II. Claims 10-11 drawn to "A co-crystal" comprising gabapentin and urea, classified in class 562, multiple subclasses.
- III. Claims 12-18, drawn to process for preparing different gabapentin salts as described in the said claims, classified in multiple classes and multiple subclasses. ***This group may be subjected to further restriction. A single disclosed species is hereby requested for search purpose.***
- IV. Claims 19 drawn to a process for "modulating the solubility of gabapentin for use in pharmaceutical compositions", classified in multiple classes and multiple subclasses. ***This group may be subjected to further restriction. A single disclosed species (organic acid required) is hereby requested for search purpose.***

V. Claims 20, drawn to a process for "modulating the dose response of gabapentin for use in a pharmaceutical composition", classified in multiple classes and multiple subclasses. **This group may be subjected to further restriction. A single disclosed species (required organic acid) is hereby requested for search purpose.**

VI. Claims 21 drawn to a method for treating a subject with a brain disorder as described in the said claim, classified in multiple classes and multiple subclasses. **This group may be subjected to further restriction. A single disclosed species (brain disorder/salt) is hereby requested for search purpose.**

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I and II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, they are different inventions because while Group II and I are drawn to two different composition of matter having different chemical reactivity and structure, and Inventions III-VI are drawn to different and particular processes, different among themselves and different from Inventions II and I.

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Inventions I and III and VI are related as product and process of use and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case it is well known that the prior art teaches alternatives treatments as those described by Invention VI and alternatives salts of the same amino acid use in the said treatments and compositions as the ones hereby described, see instant specification, page 2.

Indeed each invention has its own particular limitations and characteristics that a given reference anticipating or suggesting any of the above inventions does not necessarily discloses or suggests any of the remaining inventions under the meaning of 35 USC 102 or 35 USC 103.

Because these inventions are distinct for the reasons given above and the search required for a given Group is not required for any other Group, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete **must include an election of the invention to be examined even though the requirement be traversed** (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In the event that Applicant's election is directed to a group drawn to salts and pharmaceutical compositions thereof, and if the said salts and compositions are found allowable, the Examiner is kindly willing to rejoin methods of preparing and using the said salts limited to the scope of the allowable salts and provided that claims describing the said preparation are free from any 35 USC 112 issues.

CONCLUSION

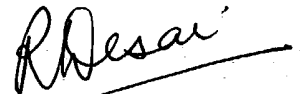
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (571) 272-0691. The examiner can normally be reached on M-F (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Primary, Rita Desai can be reached on (571) 272-0684. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hector M. Reyes PhD JD
USPTO Reg. # P-54, 846
Au 1625
November 22, 2004



Ms. Rita Desai
Primary Examiner

11/23/04.